Louisiana Medicaid
Nusinersen (Spinraza®)

The *Nusinersen (Spinraza®) Clinical Authorization Form* should be utilized to request clinical authorization for nusinersen (Spinraza®).

Additional Point-of-Sale edits may apply.

Approval Criteria

- The recipient has a diagnosis of spinal muscular atrophy (SMA):
    - Type I, also known as infantile-onset or Werdnig-Hoffmann disease (ICD-10-CM G12.0), symptoms are present at birth or by 6 months of age, unable to sit without assistance; **OR**
    - Type II (ICD-10-CM G12.1), symptoms develop between 6 months and 12 months of age, able to sit unassisted but unable to stand or walk independently; **OR**
    - Type III, also known as Kugelberg-Welander disease (ICD-10-CM G12.1), usually diagnosed between early childhood and early adolescence, able to stand and walk independently but may lose this ability later in life; **AND**
- The diagnosis of SMA is confirmed with genetic testing; **AND**
- The recipient is 16 years of age or younger at the initiation of treatment; **AND**
- The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of spinal muscular atrophy; **AND**
- The recipient has not previously received treatment with Zolgensma (onasemnogene abeparvovec-xioi); **AND**
- **ONE** of the following motor milestone tests have been performed and the results are noted on the request form:
    - For recipients ≤ 2 years of age: Hammersmith Infant Neurological Examination Section 2 (HINE-2); **OR**
    - For ambulatory recipients ≥3 years of age: Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
    - For non-ambulatory recipients >3 years of age: Revised Upper Limb Module (RULM); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no inappropriate concomitant drug therapies or disease states; **AND**
    - The recipient does not have a coexisting terminal condition or a condition with which the risk of nusinersen treatment outweighs the potential benefits.

Reauthorization Criteria

- Recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that there has been a positive clinical benefit from nusinersen therapy as evidenced by:
    - improvement or maintenance of motor skills or ability to sit, crawl, stand or walk, or new motor milestone; **AND**
    - when considering all categories of motor milestones, the number of categories which show improvement is greater than the number that shows worsening.

Duration of initial authorization: 6 months
Duration of reauthorization: 12 months

References

Spinraza (nusinersen) [package insert]. Cambridge, MA: Biogen; June 2019. Retrieved from https://www.spinraza-hcp.com/content/dam/commercial/specialty/spinraza/hcp/en_us/pdf/spinraza-prescribing-information.pdf

U.S. National Library of Medicine. Genetics Home Reference. (2018, September 25). Spinal Muscular Atrophy. Retrieved from https://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy

Revision / Date	Implementation Date
Added requirement for motor milestone testing and modified reauthorization criteria to remove point-related increases in motor milestones / September 2019	March 2020
Modified age to reflect updated prescribing information / September 2019	March 2020
Included onasemnogene abeparvovec-xioi criteria statement / July 2020	January 2021